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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/560,918 | 12/16/2005 | Matthew Baker | MER-142 | 1856 |
| <div>2387 7590 06/07/2007</div> <div>OLSON & HIERL, LTD. 20 NORTH WACKER DRIVE 36TH FLOOR CHICAGO, IL 60606</div> | | | | |
| | | | EXAMINER CARLSON, KAREN C | |
| | | | ART UNIT 1656 | PAPER NUMBER |
| | | | MAIL DATE 06/07/2007 | DELIVERY MODE PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/560,918

Applicant(s)

BAKER ET AL.

Examiner

Karen Cochrane Carlson, Ph.D.

Art Unit

1656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 April 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 and 11-16 is/are pending in the application.
- 4a) Of the above claim(s) 1-8 and 11-16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

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Applicant's election without traverse of SEQ ID NO: 1, Claim 9, in the reply filed on April 11, 2007 is acknowledged.

Claim 10 has been cancelled. The Examiner has withdrawn Claims 1-8 and 11-16 from further consideration because these claims are drawn to non-elected inventions. Claim 9 is currently under examination.

Benefit of priority is to June 26, 2003.

The disclosure is objected to because of the following informalities:

Sequences are presented throughout the specification. However, sequence identification numbers do not accompany the sequences in accordance to 37 CFR 1.821+.

Additionally, the sequence at page 4, line 1 and in Claim 9 is not found in the sequence listing. SEQ ID NO: 1 appears to be the sequence intended; however, SEQ ID NO: 1 has an Ala preceeding the N-terminal Cys.

There is no abstract present in the disclosure.

The priority at page 1 should include the foreign priority information.

Appropriate correction is required.

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 9 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims do not recite that the product has been isolated or purified

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or acted on by the hand of man such that the product is taken from its naturally occurring source. Therefore, the claimed product reads on a product of nature and is non-statutory.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In Claim 9, the sequence set forth in the claim does not correspond to SEQ ID NO: 1, that is, SEQ ID NO: 1 comprises an additional N-terminal Ala.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 9 is rejected under 35 U.S.C. 102(b) as being anticipated by Scharf et al., (1989; Primary structures of new 'iso-hirudins'. FEBS Letters 255 (1): 105-110).

Scharf et al. teach 20 naturally occurring hirudins in Fig 9. The first hirudin sequence depicted in Fig 9 is identical to SEQ ID NO: 1 from Cys28 to Glu57 (Cys2-Glu31 of instant SEQ ID NO: 1) except for the conservative amino acid difference at residue 49, wherein the corresponding residue in instant SEQ ID NO: 1 is Glu while the hirudin of Scharf et al. is Gln.

Therefore, Scharf et al. teach a peptide having a sequence consisting of at least 9 consecutive amino residues of SEQ ID NO: 1. The recited function is considered to be an inherent property to the structure.

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Scharf et al., (1989; Primary structures of new 'iso-hirudins'. FEBS Letters 255 (1): 105-110).

This rejection is being made to advance prosecution, that is, if it is intended that SEQ ID NO: 1 be Cys2-Glu31 of SEQ ID NO: 1, ie, the Ala1 is not intended to be part of the SEQ ID NO: 1.

Scharf et al. teach 20 naturally occurring hirudins in Fig 9. The first hirudin sequence depicted in Fig 9 is identical to SEQ ID NO: 1 from Cys28 to Glu57 (Cys2-Glu31 of instant SEQ ID NO: 1) except for the conservative amino acid difference at residue 49, wherein the corresponding residue in instant SEQ ID NO: 1 is Glu while the hirudin of Scharf et al. is Gln. Scharf et al. also teach hirudin having a Glu49 rather than a Gln at position 49 – see hirudin #3 of Fig 9.

It would have been obvious to a person having ordinary skill in the art to conservatively substitute amino acids in a sequence because the those skilled in this art and the MPEP

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recognize that conservative amino acid substitutions are obvious and not expected to impact function. The MPEP also recognizes that structural relationships provide the requisite motivation or suggestion to modify known compounds to obtain new compounds. Therefore, because the MPEP, and those skilled in the art, recognize that structural relationships provide suggestion to modify known compounds and that conservative amino acid substitution of amino acids is not expected to alter protein function. Suggestion to make the conservative amino acid substitutions is inherent to the structural similarity of conservative amino acids, as noted in the MPEP. The rejection under 35 USC 103 is proper and supported by the MPEP, and therefore, this argument is not persuasive. Thus, it is inherent that the polypeptide having this substitution would retain hirudin activity, further evidenced by Scharf et al.'s disclosure that hirudin #3 in Fig 9 has Glu49 and retains thrombin inhibitor activity.

MPEP 2144.08(II)(4)(c):

(c) Consider the Teachings of Structural Similarity. Consider any teachings of a "typical," "preferred," or "optimum" species or subgenus within the disclosed genus. If such a species or subgenus is structurally similar to that claimed, its disclosure may motivate one of ordinary skill in the art to choose the claimed species or subgenus from the genus, based on the reasonable expectation that structurally similar species usually have similar properties. See, e.g., *Dillon*, 919 F.2d at 693, 696, 16 USPQ2d at 1901, 1904. See also *Deuel*, 51 F.3d at 1558, 34 USPQ2d at 1214 ("Structural relationships may provide the requisite motivation or suggestion to modify known compounds to obtain new compounds. For example, a prior art compound may suggest its homologs because homologs often have similar properties and therefore chemists of ordinary skill would ordinarily contemplate making them to try to obtain compounds with improved properties."). **In the area of biotechnology, an exemplified species may differ from a claimed species by a conservative substitution ("the replacement in a protein of one amino acid by another, chemically similar, amino acid . . . [which] is generally expected to lead to either no change or only a small change in the properties of the protein."** *Dictionary of Biochemistry and Molecular Biology* 97 (John Wiley & Sons, 2d ed. 1989)). The effect of a conservative substitution on protein function depends on the nature of the substitution and its location in the chain. Although at some locations a conservative substitution may be benign, in some proteins only one amino acid is allowed at a given position. For example, the gain or loss of even one methyl group can destabilize the structure if close packing is required in the interior of domains. *James Darnell et al., Molecular Cell Biology* 51 (2d ed. 1990). The closer the physical and chemical similarities between the claimed species or subgenus and any exemplary species or subgenus disclosed in the prior art, the greater the expectation that the claimed subject matter will function in an equivalent manner to the genus. See, e.g.,

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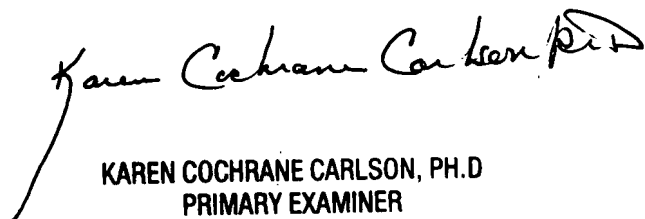
Dillon, 919 F.2d at 696, 16 USPQ2d at 1904 (and cases cited therein). Cf. Baird, 16 F.3d at 382-83, 29 USPQ2d at 1552 (disclosure of dissimilar species can provide teaching away).

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Cochrane Carlson, Ph.D. whose telephone number is 571-272-0946. The examiner can normally be reached on 7:00 AM - 4:00 PM, off alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Kathleen Kerr Bragdon can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


KAREN COCHRANE CARLSON, PH.D.
PRIMARY EXAMINER